

zinc carbonate as a source for a metal salt at col. 2, lines 31-32. It is the Examiner's position that although Sano et al does not teach a specific example containing a zinc salt of ascorbic acid-2-phosphate, one of ordinary skill in the art would have readily envisaged a zinc salt of ascorbic acid-2-phosphate as a final product resulting from the disclosed salt formation process when viewed by the other examples, e.g., ammonium or magnesium salts of ascorbic acid -2-phosphate are produced by the same salt formation process using an ammonium solution or alkali metal (e.g., magnesium) at col. 2, lines 29-34<sup>1</sup>.

The Examiner takes the alternative position that it would have been obvious to one of ordinary skill in the art to formulate the zinc salt of ascorbic acid-2-phosphate when Sano et al is taken in view of Fahim because Fahim teaches a topical composition containing a synergistic combination of zinc salt and ascorbic acid in acne treatment via stimulating collagen production and by killing the normal microflora found in the pilosebaceous ducts.

The Examiner further states that one of ordinary skill in the art would have been motivated to use zinc carbonate to make a zinc salt of ascorbic acid-2-phosphate because a zinc salt of ascorbic acid-2-phosphate would [be expected to] have the synergistic combination of the zinc ion and ascorbic acid and to maximize therapeutic efficacy. The Examiner also asserts that a zinc salt of ascorbic acid-2-phosphate would have been expected to reduce skin irritation because the synergistic combination would require a smaller dose of each active ingredient thereby minimizing skin irritation caused by excessive amounts of zinc or ascorbic acid.

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<sup>1</sup> Actually, magnesium is an alkaline earth metal, not an alkali metal.

The Examiner also takes the position that achieving less skin irritation and inhibitory effects recited in the preambles of claims 1-6 are inherent features.

Applicants respectfully traverse the rejection under 35 U.S.C. § 102(b) as improper. To anticipate the claimed invention, a reference must teach all elements of the claims and the identical invention must be shown in as complete detail as is contained in the claims. See MPEP § 2131 citing *Richardson v. Suzuki Motor, Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). As admitted by the Examiner, Sano et al does not disclose a zinc salt of ascorbic acid-2-phosphate and therefore cannot be said to anticipate the claimed invention.

Further, whether one would readily envisage the claimed invention as a final product of a disclosed salt formation process is not a test for anticipation that can be applied in this case. Whether one of ordinary skill in the art may readily envisage a claimed compound based upon the disclosure of a prior art reference is a test which may be applied when a generic chemical formula is disclosed and there is a question of whether a specific composition can be arrived at based upon selection of various substituents, which is not the situation in the present case.

In regard to the alternative rejection under 35 U.S.C. § 103(a), Applicants respectfully traverse the rejection and submit that Sano et al does not teach the final product of an ascorbic acid phosphate zinc salt and the Examiner's suggestion that one of ordinary skill in the art would nonetheless make the undisclosed ascorbic acid phosphate zinc salt based upon the disclosure of Sano et al together with the combination product of ascorbic acid and zinc salts taught by Fahim is unreasonable and improper hindsight reasoning for the reasons set forth in the Amendment filed on November 30, 2001( see page 10 of the Amendment filed on November 30, 2001, which

is incorporated herein by reference). Further, Applicants submit the following in support of the patentability of the claimed invention over the prior art of record.

As for efficacy, Sano et al only states that the salt can be used for cosmetics and medicines, but use as a preventing or treating medicine for external application to the skin, particularly acne, is not described.

Fahim only states that a combination of an ascorbic acid and zinc, which is not AP or APZ, is effective on acne or skin diseases. The combination of an ascorbic acid and zinc is effective on acne but due to skin irritation, its use as a medicine for acne is improper. This is verified in the Declaration Under 37 C.F.R. § 1.132 previously filed on November 30, 2001, (executed Declaration submitted on January 16, 2002). The significance of the experimental results of the Declaration under 37 C.F.R. § 1.132 is explained in the paragraph bridging pages 3-4 in the Preliminary Amendment filed on October 9, 2002.

The characteristic feature of the present invention is that APZ reduces skin irritation and is particularly effective as a dermal agent for acne. This effect cannot be anticipated from general salts of AP as described by the prior art. Thus, the present invention provides unexpectedly superior effects over the prior art.

Moreover, skin irritation due to zinc can be reduced by the combination of AP and a zinc salt such as APZ, which is verified in the Declaration under 37 C.F.R. § 1.132 filed on November 30, 2001, and is not described in the prior art.

Thus, skin irritation due to zinc can be reduced by the presently claimed combination of AP and APZ, but cannot be reduced with ascorbic acid. Accordingly, one of ordinary skill in the

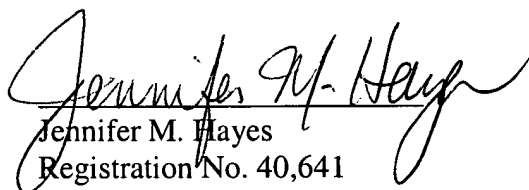
art would not have had a reasonable expectation of success in achieving the claimed invention based upon the disclosures of the Sano et al and Fahim, whether taken alone or in combination.

In view of the above Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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